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**WS**

**INDUSTRY STANDARD OF THE  
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**Evaluation requirement of indicators for medical purpose-low  
temperature steam and formaldehyde sterilization processes  
(English Translation)**

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### Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard was drafted. Shandong Provincial Center for Disease Control and Prevention, China Center for Disease Control and Prevention, environmental and health related product safety Institute, Jiangsu Provincial Center for Disease Control and Prevention, Shandong Mental Health Center, Guangdong Inspection and Quarantine Technology Center, Linyi County Safety Production Supervision Bureau of Management, Weifang Medical College.

### 1 Scope

This standard specifies the classification, general requirements, chemical indicator requirements and biological indicator requirements for medical low temperature steam formaldehyde sterilization indicators.

This standard is applicable to indicators that reflect the sterilization process of medical low temperature steam formaldehyde through changes in chemical and biological indicators.

## 2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this article.

Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB 18281.1 Sterilization biological indicators for health care products - Part 1. General Management Specification for Labeling Instructions for Disinfecting Products (2005)  
Ministry of Health (Wei Jian Fa [2005] No. 426)

## 3 Terms and definitions

The following terms and definitions apply to this document.

Low temperature steam and formaldehyde sterilization when the temperature is lower than 85 ° C, after forced air is discharged, steam formaldehyde is injected under negative pressure, and the articles to be sterilized are exposed to steam formaldehyde.

Maintain a certain period of time in a stable state to meet sterilization requirements.

Chemical indicator

The indicator and its carrier are combined in a predetermined form and exposed to one or more predetermined process variables in a low temperature steam formaldehyde sterilization procedure.

Biochemical or physical changes.

Biological indicator A bacterial carrier having a determined resistance to the low temperature steam formaldehyde sterilization process under the set conditions.

D value D value

The time required to kill 90% of the total number of specific microorganisms under set exposure conditions.

Survival time survival time; ST the maximum time that a particular microorganism tested survived under set exposure conditions.

Killing time; killing time; KT the minimum time required to kill a particular microorganism tested during exposure conditions.

### 4.1.1 Sterilization process indicator

Indicates whether the sterilized items of each individual unit have undergone a sterilization procedure, including cards, tapes, labels, and the like.

#### **4.1.2 Sterilization effect indicator**

It is used to prove whether the individual unit items have reached the set value of the selected parameter after the entire sterilization process.

#### **4.2 Biological indicators**

##### **4.2.1**

According to the structure, it can be divided into flaky biological indicators and self-contained biological indicators. The flaky biological indicators need to use positive control and negative.

Control, while self-contained biological indicators only require a positive control.

##### **4.2.2**

According to the culture time, it can be divided into conventional biological indicators and rapid biological indicators.

### **5 General requirements for indicators**

#### **5.1**

Medical low temperature steam formaldehyde sterilization process evaluation parameters should include the action time, temperature, formaldehyde concentration.

#### **5.2**

The packaging label and instructions shall comply with the requirements of the "Management Specifications for Labeling Instructions for Disinfecting Products".

#### **5.3**

The indicator shall indicate its purpose.

#### **5.4**

Indicators should be combined with different process challenge devices to simulate the most difficult parts of the sterilization factor.

#### **5.5**

Indicators should indicate storage conditions and expiration dates.

#### **5.6**

After the sterilization cycle that meets the preset parameters, the indicator changes should be consistent with the manufacturer's specified qualification requirements;

If the limit parameter does not meet or the preset parameters are unreasonable, the indicator change shall be inconsistent with the manufacturer's specified qualification

requirements.

### 5.7

Biological indicators used for routine monitoring should be used in conjunction with chemical indicators. Both are qualified to achieve sterilization.

### 5.8

The indicator packaging material and carrier should avoid the selection of materials that adsorb formaldehyde, and should not affect the use of the indicator to ensure its harmless.

### 5.9

Take the packaged indicator and place it under the storage conditions of the production mark, store it to the specified validity period, take it out and evaluate it again.

The display shall meet the technical requirements specified in this standard.

## 6.1 Sterilization process chemical indicators

The chemical indicator of the sterilization process shall be tested and meet the requirements as specified in Table 1. See Appendix A for the determination method.

Table 1 Test and performance requirements for sterilization process indicators

Test number

Test Conditions

Performance requirements Test time test temperature formaldehyde concentration A1 90 min $\pm$ 1 min 80°C $\pm$ 2°C 0 mol/L No change or change from manufacturer's specifications A2 20 s  $\pm$  5 s 60 ° C  $\pm$  0.5 ° C 1.0 mol/L  $\pm$  0.01 mol/L No change or different from the manufacturer's specified changes A3 15 min  $\pm$  15 s 70 ° C  $\pm$  2 ° C 1.0 mol/L  $\pm$  0.01 mol/L should be the same as the manufacturer's changes

**Note 1:** If the process chemical indicator is only indicated for use in a sterilization cycle at temperatures below 55 ° C or above 65 ° C, the test in Table 1 shall be as specified by the manufacturer.

The highest temperature and formaldehyde concentration are carried out.

**Note 2:** In order to prove the applicability to special processes, the manufacturer's specified low temperature steam formaldehyde sterilization procedure should be added for additional functional testing.

## 6.2 Sterilization effect chemical indicator

Sterilization effect chemical indicators shall be tested and meet the requirements in accordance with the conditions set forth in Table 2. See Appendix A for the determination method.